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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,071	02/27/2004	Yunn-Bor Yang	6653-022-999	9931
20583	7590	08/31/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SWOPE, SHERIDAN	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 08/31/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/789,071	Applicant(s) YANG ET AL.	
	Examiner Sheridan L. Swope	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 15-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0204</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claims 15-33 are pending. Claims 15-33 encompass a single invention, a mutated penicillin expandase polypeptide, and are herein examined.

Specification-Objections

The specification is objected to for failing to state, in the first sentence, that the parent application, US 10/105,319, issued as US 6,699,699 on March 2, 2004.

Abstract

The Abstract is objected to for being a single, run-on sentence and for disclosing the mutation at residue Gly⁷⁹ as S⁷⁹E instead of G⁷⁹E, as recited in the disclosure.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226

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(Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 15-22 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-3 of US Patent 6,699,699. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 15-22 and 24 herein and Claims 1-3 of US 6,699,699 are both directed to mutated penicillin expandases comprising substitutions at one or more of M⁷³, G⁷⁹, V²⁷⁵, L²⁷⁷, and C²⁸¹. The claims differ in that Claims 1-3 of US 6,699,699 also recites mutants comprising substitutions at G³⁰⁰. The portion of the specification in 6,699,699 that supports the recited methods includes embodiments that would anticipate Claims 15-22 and 24 herein, e.g., mutated penicillin expandases comprising substitutions at one or more of M⁷³, G⁷⁹, V²⁷⁵, L²⁷⁷, and C²⁸¹, which are also the penicillin expandases specifically recited in Claims 1-3 of 6,699,699. Claims 15-22 and 24 herein cannot be considered patentably distinct over Claims 1-3 of 6,699,699 when there are specifically recited embodiments (mutated penicillin expandases comprising substitutions at one or more of M⁷³, G⁷⁹, V²⁷⁵, L²⁷⁷, and C²⁸¹) that would anticipate Claims 15-22 and 24 herein. Alternatively, Claims 15-22 and 24 herein cannot be considered patentably distinct over Claims 1-3 of 6,699,699 when there are specifically disclosed embodiments in 6,699,699 that supports Claims 1-3 of that patent and falls within the scope of Claims 15-22 and 24 herein, because it would have been obvious to a skilled artisan to modify the penicillin expandases of Claims 1-3 of 6,699,699 by selecting specifically disclosed embodiments that supports those claims, i.e., mutated penicillin expandases comprising substitutions at one or more of M⁷³, G⁷⁹, V²⁷⁵, L²⁷⁷, and C²⁸¹, as disclosed in 6,699,699. One having ordinary skill in the art would have been

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motivated to do this, because such embodiments are disclosed as being preferred embodiments within Claims 1-3 of the prior patent.

Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 4 of US Patent 6,699,699. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 23 herein and Claim 4 of 6,699,699 are both directed to mutated penicillin expandases comprising substitutions at one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , G^{304} , and G^{305} . The claims differ in that Claim 4 of 6,699,699 recites the limitation of variants that must have substitutions at G^{304} or G^{305} , while Claim 23 herein recites the limitation of variants that may or may not have substitutions at G^{304} and G^{305} . The portion of the specification in 6,699,699 that supports the recited penicillin expandases includes embodiments that would anticipate Claim 23 herein, e.g., mutated penicillin expandases comprising substitutions at one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , G^{304} , and G^{305} , which are also the penicillin expandases specifically recited in Claim 4 of 6,699,699. Claim 23 herein cannot be considered patentably distinct over Claim 4 of 6,699,699 when there are specifically recited embodiments (mutated penicillin expandases comprising substitutions at one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , G^{304} , and G^{305}) that would anticipate Claim 23 herein. Alternatively, Claim 23 herein cannot be considered patentably distinct over Claim 4 of 6,699,699 when there are specifically disclosed embodiments in 6,699,699 that supports Claim 4 of that patent and falls within the scope of Claim 4 herein, because it would have been obvious to a skilled artisan to modify the penicillin expandases of Claim 4 of 6,699,699 by selecting a specifically disclosed embodiment that supports those claims, i.e., mutated penicillin expandases comprising substitutions at G^{304} or G^{305} and one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , as

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disclosed in 6,699,699. One having ordinary skill in the art would have been motivated to do this, because such embodiments are disclosed as being preferred embodiments within Claim 4 of the prior patent.

Claims 25-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 6 of US Patent 6,699,699. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 25-30 herein and Claim 6 of US 6,699,699 are both directed to mutated penicillin expandases comprising substitutions at one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , G^{304} , and G^{305} wherein, for some mutants, M^{73} is substituted with threonine, G^{79} is substituted with glutamic acid, V^{275} is substituted with isoleucine, L^{277} is substituted with lysine, and C^{281} is substituted with tyrosine, G^{300} is substituted with valine, G^{304} is substituted with lysine, and G^{305} is substituted with leucine or methionine. The claims differ in that Claims 25-30 herein also recite mutants comprising substitutions with other amino acid residues. The portion of the specification in 6,699,699 that supports the recited penicillin expandases includes embodiments that would anticipate Claims 25-32 herein, e.g., mutated penicillin expandases comprising substitutions at one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , G^{304} , and G^{305} wherein, for some mutants, M^{73} is substituted with threonine, G^{79} is substituted with glutamic acid, V^{275} is substituted with isoleucine, L^{277} is substituted with lysine, and C^{281} is substituted with tyrosine, G^{300} is substituted with valine, G^{304} is substituted with lysine, and G^{305} is substituted with leucine or methionine, which are also the penicillin expandases specifically recited in Claim 6 of 6,699,699. Claims 25-32 herein cannot be considered patentably distinct over Claim 6 of 6,699,699 when there are specifically recited embodiments (mutated penicillin expandases comprising

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substitutions at one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , G^{304} , and G^{305} wherein, for some mutants, M^{73} is substituted with threonine, G^{79} is substituted with glutamic acid, V^{275} is substituted with isoleucine, L^{277} is substituted with lysine, and C^{281} is substituted with tyrosine, G^{300} is substituted with valine, G^{304} is substituted with lysine, and G^{305} is substituted with leucine or methionine) that would anticipate Claims 25-32 herein. Alternatively, Claims 25-32 herein cannot be considered patentably distinct over Claim 6 of 6,699,699 when there are specifically disclosed embodiments in 6,699,699 that supports Claim 6 of that patent and falls within the scope of Claims 25-32 herein, because it would have been obvious to a skilled artisan to modify the penicillin expandases of Claim 6 of 6,699,699 by selecting a specifically disclosed embodiments that supports those claims, i.e., mutated penicillin expandases comprising substitutions at one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , G^{304} , and G^{305} wherein, for some mutants, M^{73} is substituted with threonine, G^{79} is substituted with glutamic acid, V^{275} is substituted with isoleucine, L^{277} is substituted with lysine, and C^{281} is substituted with tyrosine, G^{300} is substituted with valine, G^{304} is substituted with lysine, and G^{305} is substituted with leucine or methionine, as disclosed in 6,699,699. One having ordinary skill in the art would have been motivated to do this because such embodiments are disclosed as being preferred embodiments within Claim 6 of the prior patent.

Claim 33 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 6 of US Patent 6,699,699. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 33 herein and Claim 6 of 6,699,699 are both directed to mutated penicillin expandases comprising substitutions at one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , G^{304} , and G^{305} , wherein G^{300} is substituted with

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valine, G^{304} is substituted with lysine, and G^{305} is substituted with leucine or methionine. The claims differ in that Claim 6 of 6,699,699 recites the limitation of variants that must have substitutions at G^{304} or G^{305} , while Claim 33 herein recites the limitation of variants that may or may not have substitutions at G^{304} and G^{305} . The portion of the specification in 6,699,699 that supports the recited penicillin expandases includes embodiments that would anticipate Claim 33 herein, e.g., mutated penicillin expandases comprising substitutions at one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , G^{304} , and G^{305} , wherein G^{300} is substituted with valine, G^{304} is substituted with lysine, and G^{305} is substituted with leucine or methionine, which are also the penicillin expandases specifically recited in Claim 6 of 6,699,699. Claim 33 herein cannot be considered patentably distinct over Claim 6 of 6,699,699 when there are specifically recited embodiments (mutated penicillin expandases comprising substitutions at one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , G^{304} , and G^{305} , wherein G^{300} is substituted with valine, G^{304} is substituted with lysine, and G^{305} is substituted with leucine or methionine) that would anticipate Claim 33 herein.

Alternatively, Claim 33 herein cannot be considered patentably distinct over Claim 6 of 6,699,699 when there are specifically disclosed embodiments in 6,699,699 that supports Claim 6 of that patent and falls within the scope of Claim 6 herein, because it would have been obvious to a skilled artisan to modify the penicillin expandases of Claim 6 of 6,699,699 by selecting a specifically disclosed embodiment that supports those claims, i.e., mutated penicillin expandases comprising substitutions at G^{304} or G^{305} and one or more of M^{73} , G^{79} , V^{275} , L^{277} , C^{281} , G^{300} , wherein G^{300} is substituted with valine, G^{304} is substituted with lysine, and G^{305} is substituted with leucine or methionine, as disclosed in 6,699,699. One having ordinary skill in the art would

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have been motivated to do this, because such embodiments are disclosed as being preferred embodiments within Claim 6 of the prior patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.

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SHERIDAN SWOPE, Ph.D.
PATENT EXAMINER